John Morris Rubber and Plastic Additives Panel The American Chemistry Council 1300 Wilson Boulevard Arlington, VA 22209

Dear Mr. Morris:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the revised test plan and robust summaries for 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione dated July 10, 2003. EPA posted the revised submission on the ChemRTK HPV Challenge Program Web site on September 1, 2004. The submission is a partial revision of the previously submitted category for the Hindered Phenols posted January 15, 2002. I commend the ACC Rubber and Plastic Additives (RAPA) Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the RAPA Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact me at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Mark W. Townsend, Chief HPV Chemicals Branch

Enclosure

cc: O. Hernandez

C. Augustyniak

J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission: 1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione

Summary Of EPA Comments

The sponsor, Rubber and Plastic Additives (RAPA) Panel Consortium of the American Chemistry Council, submitted a revised test plan and robust summaries to EPA for 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione dated July 11, 2003, in response to EPA's comments on its original submission for the Hindered Phenols Category that were posted on the website on December 10, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on September 1, 2004. The 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione submission is a partial revision of the previously submitted category for Hindered Phenols dated December 18, 2001. The RAPA panel submitted developmental toxicity data on this chemical on February 8, 2007.

EPA has reviewed this submission and has reached the following conclusions:

- 1. <u>Physicochemical properties.</u> The submitted data are adequate for the purposes of the HPV Challenge Program.
- 2. <u>Environmental Fate.</u> The submitted data are adequate for the purposes of the HPV Challenge Program. The submitter needs to address deficiencies in the robust summaries.
- 3. Health Effects. The submitted data are adequate for the purposes of the HPV Challenge Program.
- 4. <u>Ecological Effects.</u> There are problems with the studies submitted for all three endpoints. However, because of the physicochemical properties of the chemical, EPA considers it unlikely that acute or chronic exposure would result in adverse effects to aquatic organisms, and no further testing is necessary for the purposes of the HPV Challenge Program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments On 1,3,5-Tris(3,5-Di-Tert-Butyl-4-Hydroxybenzyl)-1,3,5-Triazine-2,4,6(1H,3H,5H)-Trione Challenge Submission

Test Plan

<u>Physicochemical properties (melting point, boiling point, vapor pressure, partition coefficient, and water solubility)</u>

The data submitted for these endpoints are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, and fugacity)

The data submitted for these endpoints are adequate for the purposes of the HPV Challenge Program, but the submitter needs to provide additional information in one robust summary.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The data submitted for these endpoints are adequate for the purposes of the HPV Challenge Program, and the detailed presentation of the robust summaries was unusually well done.

Ecological Effects (fish, invertebrates, and algae)

The results of studies submitted for all three endpoints are confounded by observable precipitation of the chemical at the tested concentrations and a lack of analytical monitoring of the exposure concentrations. However, the sponsored chemical has very low solubility and a high octanol-water partition coefficient indicating reduced availability of the chemical in an aquatic environment. Therefore, EPA considers it is unlikely that acute or chronic exposure would result in adverse effects to aquatic organisms. No further testing is necessary for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Environmental Fate

Transport and distribution (fugacity). The submitter needs to add all the input values used in the fugacity estimation.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.